

REMARKS

The Office Action of February 20, 2004, has been received and reviewed. Claims 1-3, 8, 10, 12, 18, 21 and 22 are pending. Claims 1, 18 and 22 stand withdrawn. Claim 1 has been amended so as to maintain the applicants' right to rejoinder. New claims 24-26 are to be added. All claim amendments and cancellations are made without prejudice or disclaimer.

Claims 2, 3, 8, and 21 stand rejected under 35 U.S.C. § 101 as assertedly being drawn to non-statutory subject matter. Claims 2, 3, 8, and 10 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 2, 3, 8, and 10 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking sufficient written description. Claims 2 and 3 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Zhang *et al.*, Laguna *et al.* and/or Chen *et al.* Reconsideration is respectfully requested.

Restriction requirement:

The applicants thank the Examiner for rejoinder of groups II and IV, and acknowledgement of the possibility of rejoinder of the product by process claims. Claim 1 has been amended so as to maintain the applicants' right to rejoinder.

Support for the claim amendments:

Support for the amendments to claims 1 and 2 can be found throughout the specification, for example, at paragraphs 44 and 45.

Support for the amendment of claim 3 can be found throughout the specification, for example, at paragraph 88 (*see*, SIP1 and SIP7).

Support for the amendments to claims 8 and 21 can be found throughout the specification, for example, at paragraphs 48-50.

Support for new claim 24 can be found throughout the specification, for example, at paragraph 48.

Support for new claims 25 and 26 can be found throughout the specification, for example, at paragraphs 51-54.

Objection to the specification:

The specification is objected to due to asserted informalities. The present amendments update the priority claim and remove the reference to the computer readable form of the sequence listing. Reconsideration and withdrawal of the objection are respectfully requested.

Rejection under 35 U.S.C. § 101:

Claims 2, 3, 8, and 21 stand rejected under 35 U.S.C. § 101 as assertedly being drawn to non-statutory subject matter. Claims 2, 3, 8 and 21 have been amended to recite an isolated polypeptide, thereby overcoming the rejection as suggested by the Office. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph:

Claims 2, 3, 8, and 10 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite.

Claim 2 is asserted to be indefinite due to the fact that it depends from a withdrawn claim. The applicants have amended claim 2 to recite the process steps of claim 1. Thus, positive protein-protein interactions in the two-hybrid assay identify the polypeptide produced from the cDNA library component of the prey as a SMAD interacting protein. Once the SMAD interacting protein is identified, the protein may be isolated using any of the methods well known in the art.

Claim 3 is asserted to be indefinite, since it is asserted that it is unclear whether *Drosophila* zfh-1 is a member of the zinc finger/homeodomain protein family. *Drosophila* zfh-1 is a member of the zinc finger/homeodomain protein family (see, e.g., <http://sdb.bio.purdue.edu/fly/gene/zincfh11.htm>). It is also asserted that it is unclear whether the SMAD interacting protein interacts with SMAD-5. The applicants have amended claim 3 to clarify that SMAD interacting protein binds to SMAD-5.

Claims 8 and 10 are asserted to be indefinite, since the function of the functional

fragments is not defined. Independent claim 8 has been amended to define the function of the fragment.

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph:

Claims 2, 3, 8, and 10 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking sufficient written description. The claims stand rejected as allegedly lacking a sufficient description of the structure of the claimed peptides. Applicants respectfully disagree.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" (*Regents of the University of California v. Eli Lilly*, 43 U.S.P.Q.2D 1398 (Fed. Cir. 1997) (citation omitted)). By analogy, a genus of SMAD interacting proteins may be sufficiently described by way of features common to the members of the genus, as is done in claims 2 and 3. In particular, the specification describes the express structure for a representative number of species within the genus, for example, representative members of claim 3 include SIP 1 and SIP 7 (paragraph 88 of the specification). Likewise, a sufficient number of representative species are disclosed for independent claims 2 and 8.

Claims 2, 3 and 8 also recite features common to the members of the genus and provide an express method to determine whether a compound is within the scope of the claim. For example, claim 3 recites at least five (5) features common to the members of the genus. Thus, the applicants submit that the specification provides a sufficient written description for claims 2, 3, 8 and 10.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. § 102(a):

Claims 2 and 3 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Zhang *et al.*, Laguna *et al.* and/or Chen *et al.* Reconsideration is respectfully requested. The

Office alleges that the applicants have admitted that Zhang *et al.*, Laguna *et al.* and/or Chen *et al.* are prior art against the claimed invention. No such admission has been made or is made.

Furthermore, none of these references disclose an interaction between any protein and the C-terminal domain of a SMAD, as recited in the claims. Because the references do not disclose protein-protein interactions with the C-terminal domain of a SMAD, the references cannot anticipate the claims, regardless of whether or not the references constitute prior art.

Reconsideration and withdrawal of the rejection are respectfully requested.

#### CONCLUSION

In the event questions remain after consideration of these remarks and amendments, the Office is kindly requested to contact applicants' attorney at the number given below.

Respectfully submitted,



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Date: May 17, 2004  
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